UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM

DATE: 18 February 2016

SUBJECT: **Pirimiphos-methyl.** Acute and Steady-State Dietary (Food + Drinking Water) Exposure and Risk Assessments to Support Registration Review.

PC Code: 108102	**DP Barcode:** D430461
Decision No.: 477390	**Registration No.:** NA
Petition No.: NA	**Regulatory Action:** Registration Review
Risk Assessment Type: Dietary	**Case No.:** 2535
TXR No.: NA	**CAS No.:** 29232-93-7
MRID No.: NA	**40 CFR:** §180.409

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Executive Summary

Pirimiphos-methyl (*O*-[2-diethylamino-6-methyl-4-pyrimidinyl] *O,O*-dimethyl phosphorothioate) is an organophosphate insecticide registered for post-harvest use on stored corn and sorghum grains, for treatment of iris bulbs, and for application to livestock *via* ear tags. Organophosphate insecticides (OPs) may exhibit a phenomenon known as steady-state acetylcholinesterase (AChE) inhibition, which is the most sensitive endpoint for all lifestages. After repeated dosing at the same dose, the amount of AChE inhibition in a given dose remains consistent across duration.

Acute and steady-state dietary (food + drinking water) exposure and risk assessments for pirimiphos-methyl were conducted using the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID) Version 3.16. This model uses 2003-2008

food consumption data from the U.S. Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). These analyses were performed to support the Registration Review of pirimiphos-methyl. The analyses were reviewed by the DESAC on 10 December 2015.

Both the acute and steady-state dietary assessments used data from the USDA's Pesticide Data Program (PDP) for all food forms except poultry fat, which used an anticipated residue point estimate, and both assessments assumed 100% crop treated (i.e., no "zero" data in the residue distribution files). The data reflect analysis of pirimiphos-methyl only; therefore, factors derived from metabolism studies were used to account for the des-ethyl metabolite, which is a residue of concern for risk assessment. The Environmental Fate and Effects Division (EFED) provided an estimated drinking water concentration (EDWC) of 0.39 parts-per-trillion arising from the planting of treated corn grain.

Probabilistic analyses resulted in acute dietary (food + drinking water) risk estimates that are not of concern (<100% the acute population-adjusted dose (aPAD)) for the U.S. population and all population subgroups. Combined dietary risk from food + drinking water at the 99.9th percentile of exposure is <1% of the aPAD for the U.S. population and 3.6% of the aPAD for children 3-5 years old, the highest exposed population subgroup.

The DEEM acute module was used to conduct refined two-day average (steady-state) assessments. Steady-state dietary risk estimates are not of concern (<100% the steady-state population-adjusted dose (ssPAD)) for the U.S. population and all population subgroups. Combined dietary risk from food + drinking water at the 99.9th percentile of exposure is 1.2% of the ssPAD for the U.S. population and 40% of the ssPAD for children 6-12 years old, the highest exposed population subgroup.

Pirimiphos-methyl is classified as "not likely to be carcinogenic to humans" based on the lack of carcinogenic potential noted in the available studies; therefore, cancer risk is not an issue for this active ingredient.

I. Introduction

Dietary risk assessment incorporates both exposure and toxicity of a given pesticide. For the acute and steady-state assessments, the risk is expressed as a percentage of a maximum acceptable dose (i.e., the dose that HED has concluded will result in no unreasonable adverse health effects). This dose is referred to as the PAD. The PAD is equivalent to the point of departure (POD, NOAEL, LOAEL, e.g.) divided by the required uncertainty or safety factors.

For acute and steady-state (two-day average) assessments, HED is concerned when estimated dietary risk exceeds 100% of the PAD. References that discuss dietary risk assessments in more detail are available on the EPA/pesticides web site: "Available Information on Assessing Exposure from Pesticides, A User's Guide," 21-JUN-2000, web link: http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2007-0780-0001.

The steady-state assessments were conducted in the DEEM acute module using the steady-state endpoint and a point estimate for drinking water to provide an estimate of 2-day ("steady-state") average daily exposures.

The most recent dietary risk assessment for pirimiphos-methyl was conducted in 2007 (D332652, A. Parmar, 25 December 2007).

II. Food Residue Information

The existing residue chemistry database for pirimiphos-methyl is adequate for risk assessment purposes. Pirimiphos-methyl is registered for post-harvest treatment of stored field corn, sweet corn, popcorn, and sorghum grain, as well as for an ear-tag product applied to cattle.

a. Residues of Concern

The qualitative nature of the residue of pirimiphos-methyl in corn, sorghum, and livestock has been adequately identified/characterized and is understood. The HED Metabolism Assessment Review Committee determined that pirimiphos-methyl and is des-ethyl metabolite are the compounds of toxicological concern in crops and livestock tissues (D228695, J. Stokes, 15 May 1998).

b. Tolerances

Permanent tolerances are established for the residues of pirimiphos-methyl, under 40 CFR §180.409 in/on grain of field corn, popcorn, and sorghum at 8 ppm, in aspirated grain fractions at 20 ppm, and in fat and meat by-products of cattle, goats, hogs, horses, sheep, and poultry (fat only) at 0.02 ppm.

c. Residues in Fish

The USDA's Pesticide Data Program (PDP) monitored pesticide residues in catfish in 2008, 2009, and 2010 and in salmon in 2013. In general, pesticide residues would not be expected to be found in fish unless the pesticide bioaccumulates or has an aquatic use. To determine whether or not residues are present in fish, HED now routinely checks PDP monitoring data regardless of the pesticide's uses and physicochemical properties. In 2008-2010, PDP analyzed catfish samples for pirimiphos-methyl and found detectable residues (presumably from the use of treated corn in catfish chow). Those data were used in the assessment. Residues of pirimiphos-methyl were not found in salmon.

<u>Residue Data used for Acute and Steady-State Dietary Assessments</u>

Both the acute and steady-state dietary assessments used data from the USDA's Pesticide Data Program (PDP) for beef fat (extrapolated to all mammalian fat), beef liver (extrapolated to all mammalian organ meats), catfish (extrapolated to all farm-raised freshwater finfish), corn grain (extrapolated to popcorn and sorghum after removing all non-detect values; i.e., 100% crop treated), and corn syrup. For poultry fat, these analyses use the anticipated residue calculated for the last dietary assessment (D332652, A. Parmar, 25 December 2007). The data reflect analysis of pirimiphos-methyl only; therefore, factors derived from metabolism studies were used to account for the des-ethyl metabolite. For corn, the metabolism study showed a maximum of the metabolite occurring at 1/6 the level of pirimiphos-methyl, resulting in a factor of 1.17. In beef fat, the metabolite occurred at a maximum of 1/3 the level of pirimiphos-methyl (factor = 1.3),

and in poultry fat the maximum was 1/150 (factor = 1.007). Metabolism studies showed no measurable levels of the des-ethyl metabolite in organ meats, and the metabolite is not a residue of concern for drinking water.

III. Percent Crop Treated Information

A conservative assumption that 100 percent of the commodities in the assessment were treated (100% CT) was used in both the acute and steady-state dietary exposure assessments. This assumption is reflected in the "TotalZ=0" parameter setting in the residue distribution files.

IV. Drinking Water Data

The Environmental Fate and Effects Divison had provided HED with estimated residues of pirimiphos-methyl in drinking water based on planting pirimiphos-methyl-treated corn and sorghum grain and subsequent transport of residues to drinking water (D431010, G. Rothman, 1 February 2016). The environmental loading from the use of pirimiphos-methyl-impregnated ear tags was also considered, and was determined to have a negligible contribution relative to that estimated from the planting of treated grain. Estimated drinking water concentrations (EDWCs) modeled from that scenario were <0.01 ppb for both acute and chronic scenarios (Table 1, expressed in ppm). Unlike other organophosphate dietary assessments recently completed by OPP, this assessment does not use a 21-day rolling average for water).

Table 1. Summary of Estimated Surface Water and Groundwater Concentrations for Pirimiphos-methyl (Total Toxic Residues). D431010, G. Rothman, 1 February 2016

Scenario	Surface Water Conc., ppm [a]	Groundwater Conc., ppm [b]
Acute	<0.00001	<0.00001
Chronic (non-cancer)	<0.00001	<0.00001

[a] Upper-bound EDWCs in surface water calculated from FIRST model (see memo DP Barcode 328151, Dated Feb. 22, 2007 for exact results).
[2] Upper-bound EDWCs in ground water based on PRZM-GW FL Citrus scenario.

V. DEEM-FCID Program and Consumption Information

Acute and steady-state average dietary exposure assessments were conducted for pirimiphos-methyl using DEEM-FCID, Version 3.16, which incorporates 2003-2008 consumption data from USDA's NHANES/WWEIA. The data are based on the reported consumption of more than 20,000 individuals over two non-consecutive survey days. Foods "as consumed" (e.g., apple pie) are linked to EPA-defined food commodities (e.g., apples, peeled fruit - cooked; fresh or N/S; baked; or wheat flour - cooked; fresh or N/S, baked) using publicly available recipe translation files developed jointly by USDA/ARS and EPA. For chronic exposure assessment, consumption data are averaged for the entire U.S. population and within population subgroups. However, for acute exposure assessment, consumption data are retained as individual consumption events. Based on analysis of the 2003-2008 WWEIA consumption data, which took into account dietary patterns and survey respondents, HED concluded that it is most appropriate to report risk for the following population subgroups: the general U.S. population, all infants (<1 year old), children 1-2, children 3-5, children 6-12, youth 13-19, adults 20-49, females 13-49, and adults 50-99 years old.

For an acute exposure assessment, individual one-day food consumption data are used on an individual-by-individual basis. The reported consumption amounts of each food item can be multiplied by a residue point estimate and summed to obtain a total daily pesticide exposure for a deterministic exposure assessment, or "matched" in multiple random pairings with residue values and then summed in a probabilistic assessment. The resulting distribution of exposures is expressed as a percentage of the aPAD on both a user (i.e., only those who reported eating relevant commodities/food forms) and a per-capita (i.e., those who reported eating the relevant commodities as well as those who did not) basis. In accordance with HED policy, per capita exposure and risk are reported for analyses performed at all levels of refinement. However, for deterministic assessments, any significant differences in user vs. per capita exposure and risk are specifically identified and noted in the risk assessment.

For a steady-state exposure assessment, two-day average food consumptions are calculated on an individual-by-individual basis. The reported consumption amounts of each food item for each day are added together and then divided by two days. For example, if an individual reports eating 100 grams of apple on the first day and 0 grams of apple on the second day, the two-day average consumption amount would be 50 grams/day of apple [(100 grams + 0 grams)/2 days = 50 grams/day]. The resulting two-day average consumption amount can then be multiplied by a residue point estimate and summed to obtain a total daily pesticide exposure for a deterministic exposure assessment, or "matched" in multiple random pairings with residue values and then summed in a probabilistic assessment. The resulting distribution of exposures is expressed as a percentage of the PAD on both a user (i.e., only those who reported eating relevant commodities/food forms) and a per-capita (i.e., those who reported eating the relevant commodities as well as those who did not) basis. In accordance with HED policy, per capita exposure and risk are reported for analyses performed at all levels of refinement. However, for deterministic assessments, any significant differences in user vs. per capita exposure and risk are specifically identified and noted in the risk assessment.

VI. Toxicological Information

Pirimiphos-methyl is a member of the organophosphate (OP) class of pesticides. Like other OPs, the initiating event in the adverse outcome pathway (AOP)/ mode of action (MOA), for pirimiphos-methyl involves inhibition of the enzyme acetylcholinesterase (AChE) via phosphorylation of the serine residue at the active site of the enzyme. Formation of an oxon metabolite is not an issue of concern for pirimiphos-methyl. None of the guideline developmental and reproduction toxicity studies for pirimiphos-methyl demonstrated quantitative and/or qualitative susceptibility. In the acute CCA study, pups were more sensitive to RBC and brain AChE inhibition compared to adults. However, RBC and brain AChE inhibition was comparable in adults and pups after repeated exposure. The available data for pirimiphos-methyl do not allow a comparative AChE evaluation of pregnant dams and fetuses due to the absence of the gestational component in the CCA studies.

Epidemiology studies consistently identified associations with neurodevelopmental outcomes associated with OP exposure such as delays in mental development in infants (24-36 months), attention problems and autism spectrum disorder in early childhood, and intelligence decrements in school age children. Therefore, there is a need to protect children from exposures that may cause these effects; this need prevents the agency from reducing or removing the statutory FQPA Safety Factor. Thus, the FQPA 10X Safety Factor will be retained for pirimiphos-methyl for the

population subgroups that include infants, children, youths, and women of childbearing age for all exposure scenarios. The FQPA 10X Safety Factor also accounts for the lack of gestational data for pirimiphos-methyl. Endpoints and points of departure for assessing dietary risk from pirimiphos-methyl are summarized in Table 2.

Table 2. Summary of Toxicological Doses and Endpoints and Points of Departure for Pirimiphos-methyl in Dietary and Non-Occupational Human Health Risk Assessments

Exposure Scenario	Point of Departure (mg/kg/day)	Uncertainty/FQPA Factors	RFD, PAD Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary (all populations, except adults (50-99 years)	$BMDL_{10}$ = 6.07 mg/kg/day	UF_A = 10x UF_H = 10x FQPA SF = 10x [a] Total 1000	Acute RfD=0.006 mg/kg/day Acute PAD= 0.006 mg/kg/day	Acute CCA Study (MRID 49037404) in the rat BMD_{10} = 7.06 mg/kg/day Inhibition of RBC AChE in pups on PND 12.
Acute Dietary (adults (50-99 years)	$BMDL_{10}$ = 6.07 mg/kg/day	UF_A = 10x UF_H = 10x FQPA SF = 1x Total 100	Acute RfD= 0.06 mg/kg/day Acute PAD= 0.06 mg/kg/day	Acute CCA Study (MRID 49037404) in the rat BMD_{10} = 7.06 mg/kg/day Inhibition of RBC AChE in pups on PND 12.
Steady-State Dietary (all populations, except adults (50-99 years)	$BMDL_{10}$ = 0.73 mg/kg/day	UF_A = 10x UF_H = 10x FQPA SF = (UF_{DB})= 10x [a] Total=1000X	Steady State RfD=0.00073 mg/kg/day Steady State PAD = 0.00073 mg/kg/day	Repeat CCA Study (MRID 49037406) in the rat BMD_{10} = 1.01mg/kg/day Inhibition of RBC AChE in pups on PND 21
Steady-State Dietary (adults (50-99 years)	$BMDL_{10}$ = 0.73 mg/kg/day	UF_A = 10x UF_H = 10x FQPA SF = 1x Total 100	Steady State RfD = 0.0073 mg/kg/day Steady State PAD = 0.0073 mg/kg/day	Repeat CCA Study (MRID 49037406) in the rat BMD_{10} = 1.01mg/kg/day Inhibition of RBC AChE in pups on PND 21
Cancer (oral, dermal, inhalation)	Classification: "Not likely to be carcinogenic to humans."			

Point of Departure (POD) = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. NOAEL = no observed adverse effect level. LOAEL = lowest observed adverse effect level. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). $UF_{DB=}$ Database Uncertainty Factor. FQPA SF = FQPA Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. RfC = reference concentration. MOE = margin of exposure. LOC = level of concern. N/A = not applicable. [a] database uncertainty factor for uncertainty in the human dose-response relationship for neurodevelopmental effects.

VII. Results/Discussion

As stated above, for acute and steady-state assessments, HED is concerned when dietary risk exceeds 100% of the PAD. The DEEM-FCID analyses estimate the dietary exposure of the U.S. population and various population subgroups. See the Appendices for a full listing of results for acute and steady state exposures.

Acute

The results of the acute dietary (food+water) assessment for pirimiphos-methyl are summarized in Table 3. Risk estimates are below 100% of the aPAD for all population groups and are not of concern.

Table 3. Summary of Acute Dietary (Food+Water) Exposure and Risk for Pirimiphos-methyl

Population Subgroup	Acute PAD (mg/kg/day)	95th Percentile		99th Percentile		99.9th Percentile	
		Exposure (mg/kg/day)	% aPAD	Exposure (mg/kg/day)	% aPAD	Exposure (mg/kg/day)	% aPAD
General U.S. Population	0.006	0.000004	<1	0.000007	<1	0.000074	1.2
All Infants (<1 year old)	0.006	0.000008	<1	0.000012	<1	0.000093	1.5
Children 1-2 years old	0.006	0.000007	<1	0.000014	<1	0.000193	3.2
Children 3-5 years old	0.006	0.000006	<1	0.000014	<1	**0.000216**	**3.6**
Children 6-12 years old	0.006	0.000005	<1	0.000010	<1	0.000174	2.9
Youth 13-19 years old	0.006	0.000004	<1	0.000007	<1	0.000075	1.2
Adults 20-49 years old	0.006	0.000003	<1	0.000005	<1	0.000055	<1
Adults 50-99 years old	0.06	0.000002	<1	0.000004	<1	0.000040	<1
Females 13-49 years old	0.006	0.000003	<1	0.000005	<1	0.000057	<1

The highest exposure at the 99.9th percentile is in bold.

Steady State

The results of the steady-state dietary (food+water) assessment for pirimiphos-methyl are summarized in Table 4. Risk estimates are below 100% of the ssPAD for all population groups and are not of concern.

Table 4. Summary of Steady-State Dietary (Food+Water) Exposure and Risk for Pirimiphos-methyl

Population Subgroup	Steady-State PAD (mg/kg/day)	95th Percentile		99th Percentile		99.9th Percentile	
		Exposure (mg/kg/day)	% ssPAD	Exposure (mg/kg/day)	% ssPAD	Exposure (mg/kg/day)	% ssPAD
General U.S. Population	0.00073	0.000004	<1	0.000008	<1	0.000089	12
All Infants (<1 year old)	0.00073	0.000008	<1	0.000012	1.5	0.000106	14
Children 1-2 years old	0.00073	0.000006	<1	0.000017	2.2	0.000241	33
Children 3-5 years old	0.00073	0.000006	<1	0.000020	2.7	**0.000295**	**40**
Children 6-12 years old	0.00073	0.000005	<1	0.000015	2.0	0.000223	31
Youth 13-19 years old	0.00073	0.000003	<1	0.000008	1.0	0.000103	14
Adults 20-49 years old	0.00073	0.000003	<1	0.000006	<1	0.000070	9.6
Adults 50-99 years old	0.0073	0.000002	<1	0.000004	<1	0.000046	<1
Females 13-49 years old	0.00073	0.000002	<1	0.000005	<1	0.000074	10

The highest exposure at the 99.9th percentile is in bold.

VIII. Characterization of Inputs/Outputs

Both the acute and steady-state assessments are considered to be refined, with the majority of the residue inputs being from PDP monitoring data. Some conservatism is retained in the assumption of 100% crop treated for all commodities.

IX. Conclusions

Refined estimates of dietary exposure to the residues of concern for pirimiphos-methyl are not of concern. Evaluation of aggregate exposure will be conducted in the forthcoming human health aggregate risk assessment.

X. List of Attachments

Attachment 1. DEEM-FCID Residue Input File
Attachment 2. DEEM-FCID Acute Exposure Estimates
Attachment 3. DEEM-FCID Steady State Exposure Estimates
Attachment 4. RDF Files
Attachment 5. DEEM-FCID Residue Input File – Food Only
Attachment 6. DEEM-FCID Acute Exposure Estimates – Food Only
Attachment 7. DEEM-FCID Steady State Exposure Estimates – Food Only

Attachment 1. DEEM-FCID Acute and Steady-State Residue Input File.

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OPP Health Effects Division                              Ver. 3.16, 03-08-d
DEEM-FCID Acute analysis for PIRIMIPHOS-METHYL
Residue file name: C:\Users\Mike\EPA OneDrive\OneDrive for Business\Chemistry Reviews\!DEEM Runs\Pirimiphos-
methyl\108102 Pirim Me wRFDs 2015 water.R08
Analysis Date 01-11-2016            Residue file dated: 01-11-2016/13:08:58
Reference dose (aRfD) = 0.0073 mg/kg bw/day
--------------------------------------------------------------------------------
RDL indices and parameters for Monte Carlo Analysis:
Index Dist Parameter #1          Param #2    Param #3    Comment
  #   Code
----- ---- ------------          ----------- ----------- ----------
  1    6   Beef_Fat.rdf
  2    6   Beef_Liver.rdf
  3    6   Corn_Grain.rdf
  4    6   Corn_Syrup.rdf
  5    6   Catfish.rdf

  EPA      Crop Food Name                         Def Res     Adj.Factors  RDL  Comment
  Code      Grp                                    (ppm)       #1     #2   Pntr
---------- ---- --------------------------------  ----------  ------ ------ ---  -------
3100046000 31   Beef, meat byproducts              0.000500   1.000  1.000   2
3100046001 31   Beef, meat byproducts-babyfood     0.000500   1.000  1.000   2
3100047000 31   Beef, fat                          0.000500   1.300  1.000   1  Fact. 1 for des-ethyl metab.
3100047001 31   Beef, fat-babyfood                 0.000500   1.300  1.000   1  Fact. 1 for des-ethyl metab.
3100048000 31   Beef, kidney                       0.000500   1.000  1.000   2
3100049000 31   Beef, liver                        0.000500   1.000  1.000   2
3100049001 31   Beef, liver-babyfood               0.000500   1.000  1.000   2
4000096000 40   Chicken, fat                       0.000261   1.007  1.000      Fact. 1 for des-ethyl metab.
4000096001 40   Chicken, fat-babyfood              0.000261   1.007  1.000      Fact. 1 for des-ethyl metab.
4000097000 40   Chicken, skin                      0.000261   1.007  1.000
4000097001 40   Chicken, skin-babyfood             0.000261   1.007  1.000
1500120000 15   Corn, field, flour                 0.001499   1.170  1.000   3  Fact. 1 for des-ethyl metab.
1500120001 15   Corn, field, flour-babyfood        0.001499   1.170  1.000   3  Fact. 1 for des-ethyl metab.
1500121000 15   Corn, field, meal                  0.001499   1.170  1.000   3  Fact. 1 for des-ethyl metab.
1500121001 15   Corn, field, meal-babyfood         0.001499   1.170  1.000   3  Fact. 1 for des-ethyl metab.
1500122000 15   Corn, field, bran                  0.001499   1.170  1.000   3  Fact. 1 for des-ethyl metab.
1500123000 15   Corn, field, starch                0.001499   1.170  1.000   3  Fact. 1 for des-ethyl metab.
1500123001 15   Corn, field, starch-babyfood       0.001499   1.170  1.000   3  Fact. 1 for des-ethyl metab.
1500124000 15   Corn, field, syrup                 0.000250   1.170  1.000   4  Fact. 1 for des-ethyl metab.
1500124001 15   Corn, field, syrup-babyfood        0.000250   1.170  1.000   4  Fact. 1 for des-ethyl metab.
1500125000 15   Corn, field, oil                   0.001499   1.170  1.000   3  Fact. 1 for des-ethyl metab.
1500125001 15   Corn, field, oil-babyfood          0.001499   1.170  1.000   3  Fact. 1 for des-ethyl metab.
1500126000 15   Corn, pop                          0.045000   1.170  1.000   3  Fact. 1 for des-ethyl metab.
8000158000 80   Fish-freshwater finfish, farm ra   0.000500   1.000  1.000   5
3200170000 32   Goat, meat byproducts              0.000500   1.000  1.000   2
3200171000 32   Goat, fat                          0.000500   1.300  1.000   1  Fact. 1 for des-ethyl metab.
3200172000 32   Goat, kidney                       0.000500   1.000  1.000   2
3200173000 32   Goat, liver                        0.000500   1.000  1.000   2
6000304000 60   Poultry, other, fat                0.000261   1.007  1.000      Fact. 1 for des-ethyl metab.
6000305000 60   Poultry, other, skin               0.000261   1.007  1.000
3500340000 35   Sheep, meat byproducts             0.000500   1.000  1.000   2
3500341000 35   Sheep, fat                         0.000500   1.300  1.000   1  Fact. 1 for des-ethyl metab.
3500341001 35   Sheep, fat-babyfood                0.000500   1.300  1.000   1  Fact. 1 for des-ethyl metab.
3500342000 35   Sheep, kidney                      0.000500   1.000  1.000   2
3500343000 35   Sheep, liver                       0.000500   1.000  1.000   2
1500344000 15   Sorghum, grain                     0.045000   1.170  1.000   3  Fact. 1 for des-ethyl metab.
5000385000 50   Turkey, fat                        0.000261   1.007  1.000      Fact. 1 for des-ethyl metab.
5000385001 50   Turkey, fat-babyfood               0.000261   1.007  1.000      Fact. 1 for des-ethyl metab.
5000386000 50   Turkey, skin                       0.000261   1.007  1.000
5000386001 50   Turkey, skin-babyfood              0.000261   1.007  1.000
8601000000 86A  Water, direct, all sources         0.000010   1.000  1.000
8602000000 86B  Water, indirect, all sources       0.000010   1.000  1.000
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Attachment 2. DEEM-FCID Acute Exposure Estimates

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OPP Health Effects Division                                  Ver. 3.16, 03-08-d
DEEM-FCID ACUTE Analysis for PIRIMIPHOS-METHYL           NHANES 2003-2008 2-Day
Residue file: 108102 Pirim Me wRFDs 2015 water.R08
Adjustment factor #2 NOT used.
Analysis Date: 01-11-2016/13:40:45    Residue file dated: 01-11-2016/13:08:58
Acute Pop Adjusted Dose (aPAD) varies with population; see individual reports
RAC/FF intake summed over 24 hours
MC iterations = 2000; MC list in residue file; MC seed = 75; RNG = MS VB
Run Comment: ""
================================================================================

Summary calculations--per capita:

                  95th Percentile      99th Percentile     99.9th Percentile
                  Exposure   % aPAD    Exposure   % aPAD    Exposure   % aPAD
                 ---------- --------  ---------- --------  ---------- --------
Total US Population:
                  0.000004     0.01    0.000007     0.01    0.000074     0.12
All Infants:
                  0.000008     0.14    0.000012     0.21    0.000093     1.55
Children 1-2:
                  0.000007     0.12    0.000014     0.23    0.000193     3.22
Children 3-5:
                  0.000006     0.11    0.000014     0.23    0.000216     3.60
Children 6-12:
                  0.000005     0.08    0.000010     0.17    0.000174     2.89
Youth 13-19:
                  0.000004     0.06    0.000007     0.11    0.000075     1.25
Adults 20-49:
                  0.000003     0.05    0.000005     0.09    0.000055     0.92
Adults 50-99:
                  0.000002     0.00    0.000004     0.01    0.000040     0.07
Female 13-49:
                  0.000003     0.05    0.000005     0.08    0.000057     0.94
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Attachment 3. DEEM-FCID Steady State Exposure Estimates.

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OPP Health Effects Division                                  Ver. 3.16, 03-08-d
DEEM-FCID ACUTE Analysis for PIRIMIPHOS-METHYL           NHANES 2003-2008 2-Day
Residue file: 108102 Pirim Me wRFDs 2015 water.R08
Adjustment factor #2 NOT used.
Analysis Date: 01-11-2016/13:48:27    Residue file dated: 01-11-2016/13:08:58
Acute Pop Adjusted Dose (aPAD) varies with population; see individual reports
Two-Day Average Results Reported
RAC/FF intake summed over 24 hours
MC iterations = 2000; MC list in residue file; MC seed = 75; RNG = MS VB
Run Comment: ""
================================================================================

Summary calculations--per capita:
```

	95th Percentile Exposure	% aPAD	99th Percentile Exposure	% aPAD	99.9th Percentile Exposure	% aPAD
Total US Population:						
	0.000004	0.05	0.000008	0.10	0.000089	1.22
All Infants:						
	0.000008	1.04	0.000012	1.60	0.000106	14.47
Children 1-2:						
	0.000006	0.88	0.000017	2.32	0.000241	33.07
Children 3-5:						
	0.000006	0.81	0.000020	2.75	0.000295	40.44
Children 6-12:						
	0.000005	0.63	0.000015	2.02	0.000223	30.53
Youth 13-19:						
	0.000003	0.45	0.000008	1.04	0.000103	14.12
Adults 20-49:						
	0.000003	0.39	0.000006	0.77	0.000070	9.57
Adults 50-99:						
	0.000002	0.03	0.000004	0.06	0.000046	0.63
Female 13-49:						
	0.000003	0.36	0.000005	0.73	0.000074	10.07

Attachment 4. RDF Files.

Beef Fat (RDF 1)

```
'Pirimiphos_Methyl, Created by SAS Program: CreateRDF_031714, 04JUN14
'Subdirectory: G:\USDA_PDP\SAS\Chemicals\Pirimiphos, RDF Filename=Beef_Fat.rdf
'Residue=CONCEN, RPF=RPF, Brigetable=BT_Recent, PFactor=PF1, PCT=PCT_Max, LOD Rule=LOD1
'PDP Data: BAFZ (2001,2002), Total Samples=592, Total Detects=0, Total LODs=592, Total Zeros=0
'MaxPCT=1.000, Avg Residue (Detects)=., Avg Residue (TOTALS)=0.0010,
'Avg Residue (Blended, PCT=100)=0.001000, Avg HLOD (NonDetects)=0.0010
TOTALZ=0
TOTALLOD=592
LODRES=0.0010
```

Beef Liver (RDF 2)

```
'Pirimiphos_Methyl, Created by SAS Program: CreateRDF_031714, 04JUN14
'Subdirectory: G:\USDA_PDP\SAS\Chemicals\Pirimiphos, RDF Filename=Beef_Liver.rdf
'Residue=CONCEN, RPF=RPF, Brigetable=BT_Recent, PFactor=PF1, PCT=PCT_Max, LOD Rule=LOD1
'PDP Data: BLFZ (2001,2002), Total Samples=624, Total Detects=0, Total LODs=624, Total Zeros=0
'MaxPCT=1.000, Avg Residue (Detects)=., Avg Residue (TOTALS)=0.0010,
'Avg Residue (Blended, PCT=100)=0.001000, Avg HLOD (NonDetects)=0.0010
TOTALZ=0
TOTALLOD=624
LODRES=0.0010
```

Corn Grain (RDF 3)

```
'Pirimiphos_Methyl, Created by SAS Program: CreateRDF_031714, 04JUN14
'Subdirectory: G:\USDA_PDP\SAS\Chemicals\Pirimiphos, RDF Filename=Corn_Grain.rdf
'Residue=CONCEN, RPF=RPF, Brigetable=BT_Recent, PFactor=PF1, PCT=PCT_Max, LOD Rule=LOD1
'PDP Data: COGR (2007,2008), Total Samples=722, Total Detects=20, Total LODs=702, Total Zeros=0
'MaxPCT=1.000, Avg Residue (Detects)=0.045350, Avg Residue (TOTALS)=0.0017,
'Avg Residue (Blended, PCT=100)=0.001742, Avg HLOD (NonDetects)=0.0005
TOTALZ=0
TOTALLOD=702
LODRES=0.0005
0.634
0.075
0.049
0.046
0.045
0.008
0.007
0.007
0.006
0.005
0.005
0.003
0.003
0.002
0.002
0.002
0.002
0.002
0.002
0.002
```

Corn Syrup (RDF 4)

```
'Pirimiphos_Methyl, Created by SAS Program: CreateRDF_031714, 04JUN14
'Subdirectory: G:\USDA_PDP\SAS\Chemicals\Pirimiphos, RDF Filename=Corn_Syrup.rdf
'Residue=CONCEN, RPF=RPF, Brigetable=BT_Recent, PFactor=PF1, PCT=PCT_Max, LOD Rule=LOD1
'PDP Data: CYOT (1998,1999), Total Samples=408, Total Detects=0, Total LODs=408, Total Zeros=0
'MaxPCT=1.000, Avg Residue (Detects)=., Avg Residue (TOTALS)=0.0005,
'Avg Residue (Blended, PCT=100)=0.000500, Avg HLOD (NonDetects)=0.0005
TOTALZ=0
TOTALLOD=408
LODRES=0.0005
```

Catfish (RDF 5)

```
'Pirimiphos_Methyl, Created by SAS Program: CreateRDF_031714, 04JUN14
'Subdirectory: G:\USDA_PDP\SAS\Chemicals\Pirimiphos, RDF Filename=Catfish.rdf
'Residue=CONCEN, RPF=RPF, Brigetable=BT_Recent, PFactor=PF1, PCT=PCT_Max, LOD Rule=LOD1
'PDP Data: FCFR,FCFZ (2008,2009,2010), Total Samples=1479, Total Detects=9, Total LODs=1470,
'Total Zeros=0
'MaxPCT=1.000, Avg Residue (Detects)=0.007833, Avg Residue (TOTALS)=0.0010,
'Avg Residue (Blended, PCT=100)=0.001043, Avg HLOD (NonDetects)=0.0010
TOTALZ=0
TOTALLOD=1470
LODRES=0.0010
0.0229
0.0182
0.0132
0.004
0.0032
0.003
0.0027
0.0019
0.0014
```

Attachment 5. DEEM-FCID Residue Input File – Food Only

```
Filename: 108102 Pirim Me wRFDs Food Only.R08
Chemical: Pirimiphos-methyl
RfD(Chronic): .00073 mg/kg bw/day  NOEL(Chronic): 0 mg/kg bw/day
RfD(Acute): .006 mg/kg bw/day  NOEL(Acute):  0 mg/kg bw/day
Date created/last modified: 12-17-2015/14:16:28       Program ver. 3.16, 03-08-d
--------------------------------------------------------------------------------
RDL indices and parameters for Monte Carlo Analysis:
Index Dist Parameter #1        Param #2  Param #3  Comment
  #   Code
----- ---- ------------        --------  --------  -------
  1    6   Beef_Fat.rdf
  2    6   Beef_Liver.rdf
  3    6   Corn_Grain.rdf
  4    6   Corn_Syrup.rdf
  5    6   Catfish.rdf

   EPA     Crop Commodity Name                    Def Res     Adj.Factors  RDLComment
   Code     Grp                                    (ppm)       #1     #2   Pntr
---------- ---- --------------------------------  ----------  ------ ------ ---  -------
1500120000 15   Corn, field, flour                  0.001499   1.170  1.000   3  Fact 1 for des-ethyl metab.
1500120001 15   Corn, field, flour-babyfood         0.001499   1.170  1.000   3  Fact 1 for des-ethyl metab.
1500121000 15   Corn, field, meal                   0.001499   1.170  1.000   3  Fact 1 for des-ethyl metab.
1500121001 15   Corn, field, meal-babyfood          0.001499   1.170  1.000   3  Fact 1 for des-ethyl metab.
1500122000 15   Corn, field, bran                   0.001499   1.170  1.000   3  Fact 1 for des-ethyl metab.
1500123000 15   Corn, field, starch                 0.001499   1.170  1.000   3  Fact 1 for des-ethyl metab.
1500123001 15   Corn, field, starch-babyfood        0.001499   1.170  1.000   3  Fact 1 for des-ethyl metab.
1500124000 15   Corn, field, syrup                  0.000250   1.170  1.000   4  Fact 1 for des-ethyl metab.
1500124001 15   Corn, field, syrup-babyfood         0.000250   1.170  1.000   4  Fact 1 for des-ethyl metab.
1500125000 15   Corn, field, oil                    0.001499   1.170  1.000   3  Fact 1 for des-ethyl metab.
1500125001 15   Corn, field, oil-babyfood           0.001499   1.170  1.000   3  Fact 1 for des-ethyl metab.
1500126000 15   Corn, pop                          0.045000   1.170  1.000   3  Fact 1 for des-ethyl metab.
1500344000 15   Sorghum, grain                     0.045000   1.170  1.000   3  Fact 1 for des-ethyl metab.
3100046000 31   Beef, meat byproducts              0.000500   1.000  1.000   2
3100046001 31   Beef, meat byproducts-babyfood     0.000500   1.000  1.000   2
3100047000 31   Beef, fat                          0.000500   1.300  1.000   1  Fact 1 for des-ethyl metab.
3100047001 31   Beef, fat-babyfood                 0.000500   1.300  1.000   1  Fact 1 for des-ethyl metab.
3100048000 31   Beef, kidney                       0.000500   1.000  1.000   2
3100049000 31   Beef, liver                        0.000500   1.000  1.000   2
3100049001 31   Beef, liver-babyfood               0.000500   1.000  1.000   2
3200170000 32   Goat, meat byproducts              0.000500   1.000  1.000   2
3200171000 32   Goat, fat                          0.000500   1.300  1.000   1  Fact 1 for des-ethyl metab.
3200172000 32   Goat, kidney                       0.000500   1.000  1.000   2
3200173000 32   Goat, liver                        0.000500   1.000  1.000   2
3500340000 35   Sheep, meat byproducts             0.000500   1.000  1.000   2
3500341000 35   Sheep, fat                         0.000500   1.300  1.000   1  Fact 1 for des-ethyl metab.
3500341001 35   Sheep, fat-babyfood                0.000500   1.300  1.000   1  Fact 1 for des-ethyl metab.
3500342000 35   Sheep, kidney                      0.000500   1.000  1.000   2
3500343000 35   Sheep, liver                       0.000500   1.000  1.000   2
4000096000 40   Chicken, fat                       0.000261   1.007  1.000      Fact 1 for des-ethyl metab.
4000096001 40   Chicken, fat-babyfood              0.000261   1.007  1.000      Fact 1 for des-ethyl metab.
4000097000 40   Chicken, skin                      0.000261   1.007  1.000
4000097001 40   Chicken, skin-babyfood             0.000261   1.007  1.000
5000385000 50   Turkey, fat                        0.000261   1.007  1.000      Fact 1 for des-ethyl metab.
5000385001 50   Turkey, fat-babyfood               0.000261   1.007  1.000      Fact 1 for des-ethyl metab.
5000386000 50   Turkey, skin                       0.000261   1.007  1.000
5000386001 50   Turkey, skin-babyfood              0.000261   1.007  1.000
6000304000 60   Poultry, other, fat                0.000261   1.007  1.000      Fact 1 for des-ethyl metab.
6000305000 60   Poultry, other, skin               0.000261   1.007  1.000
8000158000 80   Fish-freshwater finfish, farm ra   0.000500   1.000  1.000   5
```

Attachment 6. DEEM-FCID Acute Exposure Estimates – Food Only

```
OPP Health Effects Division                                  Ver. 3.16, 03-08-d
DEEM-FCID ACUTE Analysis for PIRIMIPHOS-METHYL           NHANES 2003-2008 2-Day
Residue file: 108102 Pirim Me wRFDs Food Only.R08 Adjustment factor #2 NOT used.
Analysis Date: 12-17-2015/15:57:47    Residue file dated: 12-17-2015/14:15:39
Acute Pop Adjusted Dose (aPAD) varies with population; see individual reports
RAC/FF intake summed over 24 hours
MC iterations = 2000; MC list in residue file; MC seed = 75; RNG = MS VB
Run Comment: ""
================================================================================

Summary calculations--per capita:
```

	95th Percentile Exposure	% aPAD	99th Percentile Exposure	% aPAD	99.9th Percentile Exposure	% aPAD
Total US Population:						
	0.000003	0.01	0.000007	0.01	0.000073	0.12
All Infants:						
	0.000008	0.13	0.000012	0.20	0.000095	1.58
Children 1-2:						
	0.000006	0.11	0.000014	0.23	0.000204	3.40
Children 3-5:						
	0.000006	0.10	0.000013	0.22	0.000231	3.85
Children 6-12:						
	0.000005	0.08	0.000010	0.17	0.000164	2.73
Youth 13-19:						
	0.000003	0.06	0.000006	0.11	0.000074	1.23
Adults 20-49:						
	0.000003	0.00	0.000005	0.01	0.000055	0.09
Adults 50-99:						
	0.000002	0.00	0.000004	0.01	0.000040	0.07
Female 13-49:						
	0.000003	0.04	0.000005	0.08	0.000055	0.92

Attachment 7. DEEM-FCID Steady State Exposure Estimates – Food Only

```
OPP Health Effects Division                                  Ver. 3.16, 03-08-d
DEEM-FCID ACUTE Analysis for PIRIMIPHOS-METHYL           NHANES 2003-2008 2-Day
Residue file: 108102 Pirim Me wRFDs Food Only.R08 Adjustment factor #2 NOT used.
Analysis Date: 12-17-2015/16:14:48    Residue file dated: 12-17-2015/14:15:39
Acute Pop Adjusted Dose (aPAD) varies with population; see individual reports
Two-Day Average Results Reported
RAC/FF intake summed over 24 hours
MC iterations = 2000; MC list in residue file; MC seed = 75; RNG = MS VB
Run Comment: ""
================================================================================

Summary calculations--per capita:
```

	95th Percentile Exposure	95th Percentile % aPAD	99th Percentile Exposure	99th Percentile % aPAD	99.9th Percentile Exposure	99.9th Percentile % aPAD
Total US Population:						
	0.000003	0.05	0.000007	0.10	0.000086	1.17
All Infants:						
	0.000007	0.97	0.000011	1.53	0.000109	14.90
Children 1-2:						
	0.000006	0.81	0.000016	2.22	0.000240	32.83
Children 3-5:						
	0.000006	0.77	0.000020	2.71	0.000285	39.07
Children 6-12:						
	0.000004	0.60	0.000014	1.97	0.000213	29.13
Youth 13-19:						
	0.000003	0.43	0.000007	1.02	0.000096	13.21
Adults 20-49:						
	0.000003	0.04	0.000005	0.07	0.000069	0.95
Adults 50-99:						
	0.000002	0.02	0.000004	0.05	0.000044	0.61
Female 13-49:						
	0.000002	0.34	0.000005	0.69	0.000073	9.99